IN THE MATTER OF

JEFFREY SHERR, P.D.

LICENSE No: 08902

Respondent

BEFORE THE

* STATE BOARD

* OF PHARMACY

CASE No.: 10-079

RECEIVED JUL 1 4 2010 Board of Phermacy

CONSENT ORDER

Based upon information received and a subsequent investigation by the Maryland Division of Drug Control ("DDC"), and subject to the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. §§ 12-101 et seq. (2009 Repl. Vol.) and the Maryland Administrative Procedure Act, Md. State Gov't Code Ann. §10-226(c) (2009 Repl. Vol.), the State Board of Pharmacy (the "Board") issued an Notice of Intent to Summarily Suspend dated March 25, 2010 to Jeffrey Sherr, P.D., License Number 08902, (the "Respondent"). Specifically, the Board found reliable evidence demonstrating that the public health, safety or welfare imperatively required emergency action.

On May 12, 2010, the Board held a show cause hearing before a quorum of the Board to allow the Respondent the opportunity to show cause why the Respondent did not pose an imminent threat to the public health, safety or welfare. Prior to the show cause hearing, the State and the Respondent, by and through his attorney, discussed settlement negotiations, which were presented to the Board. The Respondent and the Board agree to resolve the matter by way of this Consent Order with the terms contained herein.

FINDINGS OF FACT

- 1. The Respondent is licensed to practice pharmacy in the State of Maryland under License Number 08902. The Respondent was first licensed on July 26, 1978. The Respondent's license expires on November 30, 2010.
- 2. At all times relevant, Apple Discount Drugs ("Apple") was authorized to operate a pharmacy in the State of Maryland. Apple currently holds a permit to operate a pharmacy under permit number P01701. Apple's October 19, 2009 Renewal Application to the Board was signed by the Respondent. Apple is owned and/or operated by the Respondent.
- 3. At all times relevant, Apple was operating a retail pharmacy at 404 N. Fruitland Boulevard, Salisbury, Maryland 21801.¹
- 4. On or about January 28, 2010, the Maryland Division of Drug Control ("DDC") received a facsimile from Company A² regarding a suspicious order placed by Apple on January 27, 2010. The order was for 12,000 tablets of Carisoprodol 350 mg. The order was suspicious because Apple had ordered only 500 dosage units in the previous 12 months. Carisoprodol is a muscle relaxant known for having a high incidence of abuse. When Company A inquired about the large order, the Respondent explained that it had recently begun "mail service" and Carisoprodol is a popular drug.

not used in this Consent Order. The Respondent may obtain a listing of the names from the Administrative Prosecutor.

Apple has additional pharmacy locations at 1500 Pemberton Drive, Salisbury, Maryland 21801 and 314 Franklin Street, Suite 600, Berlin, Maryland 21811. Apple also operates a home infusion pharmacy at it's N. Fruitland Boulevard location, which is Apple's primary location.
 To protect confidentiality, names of individuals and/or companies other than the Respondent are

- 5. On March 8, 2010, DDC visited Apple to conduct a routine inspection and to investigate whether the Respondent was conducting a Internet/mail order operation in the pharmacy.
- 6. On March 8, 2010, DDC inspectors met with the Respondent, who initially denied that he was currently operating an Internet pharmacy business out of his retail pharmacy. The Respondent stated that in 2008, he briefly operated an Internet pharmacy business utilizing a Delaware physician who prescribed Tramadol.
- 7. The Respondent left the inspectors briefly to obtain a requested report. Upon his return, while the DDC inspectors were reviewing the usage report for Carisoprodol in the Respondent's retail pharmacy, the Respondent admitted that he had been untruthful with the DDC inspectors. The Respondent altered his statement and admitted to conducting an Internet pharmacy business from his N. Fruitland Boulevard location since December 2009.
- 8. The Respondent stated that he was dispensing three drugs through his Internet pharmacy, but was, in fact, dispensing four drugs: Carisoprodol 350 mg (Soma), Cyclobenzaprine 10 mg (Flexeril), Tramadol 50 mg, and Butalbital/APAP/Caffeine 5mg/325mg/40 mg (Fioricet). Of the four drugs being dispensed by the Respondent's Internet pharmacy, only Fioricet is a controlled drug (Schedule III) in the Maryland Drug Schedule. Fioricet is not a DEA scheduled drug.

³ Cyclobenzaprine (Flexeril) is a muscle relaxant used to treat skeletal muscle conditions such as pain or injury. Tramadol is an opioid analgesic used to treat moderate to severe pain. Butalbital/APAP/Caffeine (Fioricet) is a combination drug product used to treat tension headaches. Butalbital is habit-forming and has the potential for abuse.

- 9. The Respondent maintained separate prescriptions records, inventory records, and financial records for the Internet and retail pharmacies.
- 10. The Respondent's Internet pharmacy business operated as follows: Individuals are able to obtain prescription drugs by accessing a website, furnishing certain cursory information on a questionnaire, including medical history, and may submit to a telephone consultation. No physical exams are conducted, and a valid doctor-patient relationship is not established. The physicians prescribing the medications are not located in Maryland and the patients are located all over the United States.
- 11. The DDC investigation revealed that the Respondent entered into agreements with Internet Intermediary Company A ("Intermediary A") and Internet Intermediary Company B ("Intermediary B"). The Respondent would receive prescriptions through the Internet, fill the prescriptions and ship the medication directly to the patient.
- 12. The Respondent received a payment of \$5.00 for each prescription filled plus the cost of the drugs dispensed. For the week of March 2, 2010, Intermediary A paid the Respondent \$1422.80 for 124 prescriptions. For the same time period, Intermediary B paid the Respondent \$3259.56 for 285 prescriptions.
- 13. According to the documentation gathered during the DDC investigation, during the three month period in which the Respondent operated an Internet pharmacy, approximately 1000 prescriptions were filled.
 - 14. Prescriptions were mailed to patients in at least 30 states.

- 15. The prescriptions received through Intermediary A utilized the same three physicians. Two of the three physicians were located in Pennsylvania and one physician was located in California.
- 16. The prescriptions received through Intermediary B utilized one physician, who was located in Delaware.
- 17. During the inspection, the DDC inspectors reviewed invoices and found three orders for Carisoprodol for a total of 12,000 tablets.
- 18. The DDC inspectors conducted an inventory of drugs found in the Respondent's Internet pharmacy area. The following is a list of the names and quantities of drugs found in the Internet pharmacy area:⁴

# bottles x # pills	Name & Strength	Total Pilis
50 x 180	Tramadol 50 mg vials	9000
1 x 90	Tramadol 50 mg vials	90
1 x 60	Tramadol 50 mg vials	60
32 x 1000	Tramadol 50 mg by Amneal	32,000
1 x 50	Tramadol 50 mg by Amneal	50
19 x 1000	Carisoprodol 350 mg by Qualitest	19,000
1 x 50	Carisoprodol 350 mg by Qualitest	50
16 x 1000	Carisoprodol 350 mg by Watson	16,000
1 x 25	Carisoprodol 350 mg by Watson	25
31 x 500	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg by Watson	15,500
1 x 100	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg by Watson	100
50 x 90	Tramadol 50 mg in vials	4,500
4 x 30	Tramadol 50 mg in vials	120
2 x 60	Tramadol 50 mg in vials	120
4 x 30	Carisoprodol 350 mg in vials	120
3 x 60	Carisoprodol 350 mg in vials	180
29 x 90	Carisoprodol 350 mg in vials	2610
2 x 30	Carisoprodol 350 mg in vials	60
8 x 60	Carisoprodol 350 mg in vials	480

⁴ Also found in the Internet pharmacy area were 110 Federal Express padded envelopes waiting to be shipped.

1 x 250	Cyclobenzaprine 10 mg by Watson	250
21 x 90	Cyclobenzaprine 10 mg by Watson	1890
6 x 30	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	180
5 x 60	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	300
22 x 120	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	2640
32 x 90	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials	2880
47 x 90	Carisoprodol 350 mg in vials⁵	4230
22 x 180	Tramadol 50 mg in vials with prescription labels	3960
1 x 60	Tramadol 50 mg in vials with prescription labels	60
1 x 90	Tramadol 50 mg in vials with prescription labels	90
5 x 120	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials with prescription labels	600
5 x 90	Butalbital/APAP/Caffeine 50mg/ 325mg/40mg in vials with prescription labels	. 450
6 x 90	Carisoprodol 350 mg in vials with prescription labels	540

Total Carisoprodol 350 mg tabs =	43,295
Total Butalbital/APAP/Caffeine 50mg/ 325mg/40mg tabs =	
Total Cyclobenzaprine 10 mg tabs =	
Total Tramadol 50 mg tabs =	50,050

- 19. While inspecting the Respondent's Internet pharmacy area, the DDC inspectors found three-part labels for drugs awaiting shipping. The labels included: (1) a shipping label, (2) a prescription bottle label, and (3) the prescription itself, which contained the prescribing physician's electronic signature.
- 20. Prescriptions for controlled substances require either a written prescription signed by a prescribing practitioner, or a facsimile received by facsimile equipment of a written signed prescription transmitted to the pharmacy.

⁵ Filled prescriptions walting to be mailed.

All of the prescriptions being filled by the Respondent's Internet pharmacy operation were generated using a computer with attached printer located in the Internet pharmacy area. The Internet intermediaries generated the labels, which were then printed by the Respondent.

21. In the Internet pharmacy area, DDC inspectors found that the Respondent repackaged the medications in prescription bottles without proper labeling. Each individual, repackaged prescription bottle had a small piece of paper affixed to the lid or to the plastic bin in which the bottles were stored. On the affixed piece of paper was a handwritten, abbreviated name for the medication that was inside the bottle, an abbreviation for the manufacturer's name and the quantity of tablets in the bottle. The bottles were not labeled with a lot number or an expiration date.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent violated the following:

Md. Health Occ. Code Ann. § 12-313

- (b) In general. Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant for a pharmacists license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:
- (25) Violates any rule or regulation adopted by the Board[.] Code Md. Regs. ("COMAR") tit. 10, § 34.10:
 - .01 Patient Safety and Welfare.

A. A pharmacist shall:

- (1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:
 - (a) United States Code, Title 21,
 - (b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,
 - (c) Health Occupations Article, Title 12, Annotated Code of Maryland,
 - (d) Criminal Law Article, Title 5, Annotated Code of Maryland, and
 - (e) COMAR 10.19.03;

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist[.]

COMAR 10.19.03.07C:

Purpose of Issue of Prescription

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§ 5-501 – 5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of the law relating to controlled dangerous substances.

COMAR 10.19.03.09A:

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

ORDER

Based on agreement of the parties, it is therefore this __/5 day of July 2010, by an affirmative vote of the Board, hereby:

ORDERED that the Respondent's license to practice pharmacy in the State of Maryland is hereby placed on PROBATION for a period of at least three (3) years, subject to the following terms and conditions:

- 1. Within the first twelve (12) months of the probationary period, the Respondent shall successfully complete twelve (12) continuing education credits in substance abuse treatment and detection. The twelve (12) continuing education credits shall include the successful completion of the continuing education course presented by the Pharmacist Education and Advisory Council ("PEAC") or other similar Board-approved course. This requirement is in addition to the thirty (30) continuing education credits necessary for license renewal;
- 2. Within the first twelve (12) months of the probationary period, the Respondent shall write an article discussing a pharmacist's duty to verify the validity of prescriptions, with a focus on insuring a legitimate prescriber-patient relationship. Subject to the Board's discretion, such article may be posted anonymously in the Board's newsletter;
- 3. Within the first twelve (12) months of the probationary period, the Respondent shall write an article discussing the distinction between mail order pharmacy practices and Internet pharmacy practices, both legal and illegal. Subject to the Board's discretion, such article may be posted anonymously in the Board's newsletter;
- 4. Within the first ninety (90) days of the probationary period, the

- Respondent shall take and pass the Multistate Pharmacy Jurisprudence Examination ("MPJE"); and
- 5. Within the first two (2) years of the probationary period, the Respondent shall each year complete fifty (50) hours of community service, for a total of one hundred (100) hours, and provide the Board with documentation of such completion; and it is further

ORDERED that the Respondent shall pay a fine in the amount of \$10,000, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and it is further

ORDERED that the Respondent shall make a charitable contribution in the amount of \$16,000 to a non-health-related non-profit organization, reflecting a divestment of the profits gained from the Respondent's Internet pharmacy operation, and provide documentation thereof by September 1, 2010; and it is further

ORDERED that the Respondent agrees not to own or operate an Internet pharmacy operation, although nothing in this Order shall prohibit the Respondent from receiving and processing electronic prescriptions and refills in a manner consistent with applicable laws and regulations; and it is further

ORDERED that the Respondent shall bear all expenses associated with this Order; and it is further

ORDERED that the Respondent shall at all times cooperate with the Board's monitoring, supervision, and investigation of the Respondent's compliance with the terms and conditions of this Consent Order; and it is further

ORDERED that after three (3) years from the date of this Consent Order, the Respondent may submit a written petition to the Board requesting termination

of probation. After consideration of the petition, the probation may be terminated, through an order of the Board. The Board shall grant the termination if the Respondent has fully and satisfactorily complied with all of the probationary terms and conditions and there are no pending complaints related to the charges;

and it is further

ORDERED that if the Respondent violates any of the terms and conditions of Probation and this Consent Order, the Board, in its discretion, after notice and an opportunity for a show cause hearing before the Board may impose any appropriate sanction under the Act, including an additional probationary term with conditions of probation, reprimand, suspension, revocation and/or a monetary penalty; and it is further

ORDERED that the Respondent shall practice according to the Maryland Pharmacy Act and in accordance with all applicable laws, statutes and regulations pertaining to the practice of pharmacy; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Maryland State Board of Pharmacy and is therefore a public document for purposes of public disclosure, pursuant to the Public Information Act, State Gov't § 10-611 *et seg.* and COMAR 10.34.01.12.

Michael N. Souranis, P.D., President Maryland Board of Pharmacy

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CONSENT

I, Jeffrey Sherr, P.D., acknowledge that I have had the opportunity to consult with counsel before signing this document. By this Consent, I accept to be bound by this Consent Order and its conditions and restrictions. I waive any rights I may have had to contest the Findings of Fact and Conclusions of Law.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections as provided by law. I acknowledge the legal authority and the jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order. I also affirm that I am waiving my right to appeal any adverse ruling of the Board that might have followed any such hearing.

I sign this Consent Order after having had an opportunity to consult with counsel, without reservation, and I fully understand and comprehend the language, meaning and terms of this Consent Order. I voluntarily sign this Order, and understand its meaning and effect.

Date

Jeffrey Sherr, P.D.

Respondent

Reviewed and approved by:

Laurence B. Russell, Esq. Attorney for the Respondent

<u>NOTARY</u>

STATE OF MARYLAND
CITY/COUNTY OF WUSMICO:
I HEREBY CERTIFY that on this 21 day of July , 2010,
before me, a Notary Public of the foregoing State personally appeared Jeffrey
Sherr, P.D. License Number 08902, and made oath in due form of law that
signing the foregoing Consent Order was his voluntary act and deed, and the
statements made herein are true and correct.
AS WITNESSETH my hand and notarial seal. Shighth J. Albert Notary Public
My Commission Expires: 08/01/20(0